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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,711	12/12/2001	Jennifer June Brown	ENZ-57 (CIP) (C)	4374

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EXAMINER	
FALK, ANNE MARIE	
ART UNIT	**PAPER NUMBER**
1632	

MAIL DATE	DELIVERY MODE
08/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/042,711	BROWN ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-74* is/are pending in the application.

4a) Of the above claim(s) *34-38,42,44-48,52-57 and 64-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-41, 43, 49-51, 58-63, and 69-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 December 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on May 2, 2007 has been entered. Claims 46-48 and 65 have been amended. The remarks filed August 10, 2005 (hereinafter referred to as "the response") are considered herein.

Applicants' election of Group III, Claims 39-41, 43, 49-51, 58-63, and 69-74 in the response filed June 21, 2006 is acknowledged. The elected invention is drawn to a method for developing a therapeutic procedure in a model animal system (*in vivo* testing of a procedure).

Claims 34-74 are pending in the instant application.

Claims 34-38, 42, 44-48, 52-57, and 64-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on June 21, 2006.

Claims 39-41, 43, 49-51, 58-63, and 69-74 are examined herein.

Priority

Applicant's claim for domestic priority under 35 U.S.C. § 120 is acknowledged. However, the non-provisional applications upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for Claims 39-41, 43, 49-51, 58-63, and 69-74 of this application. The earlier-filed application does not disclose an animal model as recited in the instantly claimed methods.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 39-41, 43, 49-51, 58-63, and 69-74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of *Tupaia belangeri* infected with HIV or HBV in the claimed method for developing a therapeutic procedure, does not reasonably provide enablement for the use of any animal model of any species or for other human pathogens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to a method for developing a therapeutic procedure, wherein the method involves the use of any lower primate animal model as recited in the claims.

The specification fails to provide an enabling disclosure for the use of any lower primate animal model for any human pathogen. The claims encompass the use of any lower primate species as a model for infection with any human pathogen. However, the specification only discloses *Tupaia belangeri* as an animal model for HBV and HIV infections. No guidance is offered with regard to how one skilled in the art would develop other lower primate animal models for human pathogens. No other human pathogens were examined for their capacity to infect any lower primate animal species. No other lower primate animal species were examined for their susceptibility to any human pathogen. There are numerous human pathogens including bacterial, viral, protozoan, and parasitic pathogens. The claims cover the use of any lower primate animal species infected with any human pathogen. No guidance is offered with regard to the numerous parameters that must be examined to determine if one or more of the lower primate species of animals is susceptible to infection by a single human pathogen. Furthermore, genetic modification may be used to render a lower primate animal susceptible to infection by a human pathogen. The claims encompass genetically modified animals, but the specification does not disclose any genetic modifications that could be made to render a given animal susceptible to infection by a given human pathogen. The instant specification only deals with two viral pathogens and their infectivity in a single

species of animal. Animal models of human infectious disease are notoriously unpredictable as evidenced by the numerous attempts to produce or identify a suitable animal model for HIV infection (see Lewis et al., 1995). Lewis et al. (1995) discuss the many problems that exist with regard to the disease characteristics displayed by the best animal models for HIV infection. None of the animal models exhibit the ideal characteristics as outlined in Box 1, page 144. Thus, despite an enormous amount of data on the HIV virus and its role in causing AIDS and despite intense efforts to generate an adequate animal model, significant deficiencies remain.

Given the lack of specific guidance in the specification with regard to generating or identifying lower primate animal models for human pathogens, the limited working examples disclosed, and the unpredictability in the art for developing lower primate animal models of human infectious diseases, one skilled in the art would have been required to engage in undue experimentation to produce the claimed lower primate animal models and to use the animal models in the claimed methods.

Applicants have not presented any arguments directed to this ground of rejection.

Written Description

Claims 39-41, 43, 49-51, 58-63, and 69-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to the use of a lower primate animal model for a human pathogen and methods for developing a therapeutic procedure.

The claims encompass the use of any lower primate animal species as a model for any human pathogen in the claimed methods. However, the specification only discloses two animal model systems. *Tupaia belangeri* were shown to be susceptible to infection by HBV and HIV-1. No other human

pathogens were examined for their capacity to infect any animal species. No other animal species were examined for their susceptibility to any human pathogen. There are numerous human pathogens including bacterial, viral, protozoan, and parasitic pathogens. The claims cover the use of any lower primate animal species. Furthermore, genetic modification may be used to render a lower primate animal susceptible to infection by a human pathogen. The claims encompass genetically modified lower primate animals, but the specification does not disclose any genetic modifications that could be made to render a lower primate animal susceptible to infection by a human pathogen. The instant specification only deals with two viral pathogens and their infectivity in a single species of lower primate animal. Thus, the specification does not disclose a representative number of model systems that include a representative number of animal species in combination with a representative number of human pathogens. In analyzing whether a written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In this case, only two animal models are disclosed. Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. In this case, no other relevant identifying characteristics have been disclosed. The specification does not teach a generally applicable methodology that can be used to identify animal species that can be productively infected with a given human pathogen. This limited information regarding the claimed embodiments is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of the full scope of lower primate animal models at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

With regard to the claimed methods for developing a therapeutic procedure, adequate written description is not provided. The specification does not disclose any product or process developed or derived from any animal model as set forth in the claims. Even as relates to the disclosed *Tupaia* animal models, no screening methods are disclosed as such. The absence of any written description of screening

methods as claiemd does not satisfy the written description requirement for the claimed genus. Thus it is concluded that the written description requirement is not satisfied for the claimed methods.

Applicants have not presented any arguments directed to this ground of rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40, 41, 51, 58-63, and 71-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51 and 58-63 are indefinite in their recitation of "secondary disease manifestations" because the specification does not define a "secondary disease manifestation." The specification states on page 2, lines 6-7 that "secondary manifestations can include inflammation, fibrosis, induced auto-immunity, apoptosis and cancer." These are non-limiting examples of potential secondary manifestations, but do not serve to define what a secondary manifestation actually is. The specification also refers to "primary and secondary disease manifestations" (p. 7, lines 18-19), but does not distinguish one from the other. One skilled in the art would not know what constitutes a secondary disease manifestation. Thus, the metes and bounds of the claims are not clearly set forth.

At pages 22-23, Applicants cite several portions of page 2 of the specification. However, the cited sections do not further define the term, but only refer to non-limiting examples of potential secondary manifestations. The metes and bounds of the claims are not clearly set forth.

Claims 40, 59, and 70 are indefinite in their recitation of "wherein said lower primate comprises a member of the genus Tupaia" because an animal cannot comprise anything more than one animal. Use of the phrase "wherein the lower primate belongs to the genus Tupaia" is recommended.

At page 24 of the response, Applicants review the meaning of the transitional term comprises, but this definition fails to explain how one animal can "comprise" another animal.

Claim 41 is indefinite in its recitation of "comprises" because it is unclear how a human retrovirus can "comprise" HIV-1, HIV-2, HTLV-1 or HTLV-2. Use of the term "comprises" necessarily implies that the retrovirus can be made up of more than one type of virus. It cannot. A retrovirus is a single, distinct entity that cannot be subdivided into parts. A "retrovirus" refers to a whole pathogen and therefore cannot "comprise" HIV plus something else. Substitution of "is" for "comprises" would be remedial.

At page 24 of the response, Applicants review the meaning of the transitional term comprises, but this definition fails to explain how one virus can "comprise" another virus.

Claim 60 is indefinite in its recitation of the phrase "wherein said human pathogen comprises a human retrovirus." Claim 61 is indefinite in its recitation of "wherein said human retrovirus comprises HIV 1, HIV 2, HTLV-1 or HTLV-2." Claim 62 is indefinite in its recitation of "wherein said human pathogen comprises HBV or HCV." Claim 71 is indefinite in its recitation of "wherein said human pathogen comprises a human retrovirus." Claim 72 is indefinite in its recitation of "wherein said human retrovirus comprises HIV 1, HIV 2, HTLV-1 or HTLV-2." Claim 73 is indefinite in its recitation of "wherein said human pathogen comprises HBV or HCV." As discussed in the preceding paragraph, the term "comprises" cannot be used in this context because HBV is a human pathogen and therefore cannot be only a part of a human pathogen as implied by the use of the term "comprises."

At page 24 of the response, Applicants review the meaning of the transitional term comprises, but this definition fails to explain how one virus can "comprise" another virus.

Claim Rejections - 35 USC ∋ 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 69, 70, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Yan et al. (1996).

Yan et al. (1996) disclose that *Tupaia belangeri* can be experimentally infected with human hepatitis B virus (HBV). Infection can be prevented by immunization with hepatitis B vaccine.

Thus, the claimed invention is disclosed in the prior art.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

/Anne-Marie Falk/
Primary Examiner, Art Unit 1632